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Date of the judgement

2015.11.17

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Case Number

2014 (Gyo-Hi) 356

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Reporter

Minshu Vol. 69, No. 7

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Title

Judgment concerning a case in which, due to the existence of approval of manufacturing and sale of a pharmaceutical product that had been issued prior to another approval of manufacturing and sale of the pharmaceutical product for which an application for registration of extension of the duration of a patent right was filed, the approval stated as the reason for the application is not deemed to have been necessary to obtain

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Case name

Case to seek revocation of a trial decision

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Result

Judgment of the Third Petty Bench, dismissed

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Court of the Second Instance

Intellectual Property High Court, Judgment of May 30, 2014

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Summary of the judgement

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1. Where, prior to the approval of manufacturing and sale of a pharmaceutical product under the

Pharmaceuticals and Medical Devices Act for which an application for registration of extension of the duration of a patent right was filed, another approval of manufacturing and sale of the pharmaceutical product had been granted under said Act with regard to the same patented invention, and if, as a result of the comparison between them with regard to the matters to be examined that would directly affect the substantial identity of the relevant products as a pharmaceutical product in light of the type or subject of the patent to which the application for registration of extension pertains, the scope of the manufacturing and sale of the pharmaceutical product subject to the prior approval is deemed to include the manufacturing and sale of the pharmaceutical product subject to the approval stated as the reason for the application, the approval stated as the reason for the application is not deemed to have been necessary to obtain for the working of the patented invention to which the application for registration of extension pertains.

2. Where, prior to the approval of manufacturing and sale of a pharmaceutical product under the Pharmaceuticals and Medical Devices Act for which an application for registration of extension of the duration of a patent right was filed, another approval of manufacturing and sale of the pharmaceutical product had been granted under said Act with regard to the same patented invention, and given the following circumstances (1) to (3) as explained in the judgment, the scope of the manufacturing and sale of the pharmaceutical product subject to the prior approval is not deemed to include the manufacturing and sale of the pharmaceutical product subject to the approval stated as the reason for the application:

(1) The patented invention covered by the patent right relates to a composition for treating cancer, comprising a therapeutically effective amount of vascular endothelial growth factor antagonist, and thus it is an invention of a product for which the subject matter is the ingredient of a pharmaceutical product; and the matters to be examined when issuing said two approvals, which would directly affect the substantial identity of the relevant products as a pharmaceutical product, are the ingredients, quantity, dosage, administration, effectiveness, and effect of the pharmaceutical product;

(2) The dosage and administration of the pharmaceutical product subject to the prior approval are described as "in combination with other anticancer drugs, adults are ordinarily intravenously infused with bevacizumab at a dose of 5 mg/kg (weight) or 10 mg/kg (weight) at administration intervals of at least two weeks," whereas the dosage and administration of the pharmaceutical product subject to the approval stated as the reason for the application for registration of extension are described as "in combination with other anticancer drugs, adults are ordinarily intravenously infused with bevacizumab at a dose of 7.5 mg/kg (weight) at administration intervals of at least three weeks"; and

(3) The prior approval did not permit the manufacturing and sale of the pharmaceutical product,

which is subject to the approval stated as the reason for the application for registration of extension, for the purpose of conducting the combination treatment of XELOX treatment (giving internal medicine and administering a two-hour infusion in a three-week treatment cycle) and bevacizumab treatment; but the approval stated as the reason for the application for registration of extension made it possible to manufacture and sell that product for this purpose for the first time.

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References

(Concerning 1 and 2) Article 67, paragraph (2) and Article 67-3, paragraph (1), item (i) of the Patent Act, Article 14, paragraph (1), the main body of paragraph (2), item (iii), and paragraph (9) of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc. (Pharmaceuticals and Medical Devices Act)

Patent Act

Article 67

(2) Where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Acts that are intended to ensure the safely, etc. or any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition is necessary to obtain for the working of the patented invention, the duration of the patent right may be extended, upon the filing of a request for the registration of extension of the duration, by a period not exceeding 5 years.

Article 67-3

(1) Where an application for the registration of extension of the duration of a patent right falls under any of the following items, the examiner shall render the examiner's decision to the effect that the application is to be refused:

(i) where the disposition designated by Cabinet Order under Article 67(2) is not deemed to have been necessary to obtain for the working of the patented invention;

Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc.

(Approval of Manufacturing and Sale of Pharmaceuticals, Quasi-Pharmaceutical Products and Cosmetics)

Article 14

(1) A person who intends to manufacture and sell pharmaceuticals (excluding pharmaceuticals designated by the Minister of Health, Labour and Welfare according to the criteria specified thereby), quasi-pharmaceutical products (excluding quasi-pharmaceutical products designated by the Minister of Health, Labour and Welfare according to the criteria specified thereby), or cosmetics containing

ingredients designated by the Minister of Health, Labour and Welfare must obtain approval from the Minister of Health, Labour and Welfare for the manufacturing and sale thereof for each item.
(2) The approval referred to in the preceding paragraph shall not be granted if any of the following items applies:
(iii) as a result of the examination of the name, ingredients, quantity, dosage, administration, effectiveness, effect, side effects and other matters relating to the quality, efficacy and safety of the pharmaceutical, quasi-pharmaceutical or cosmetic product to which the application pertains, the product falls under any of the following cases (a) to (c):
(9) If a person who has obtained the approval referred to in paragraph (1) intends to change any of the matters approved for the relevant product (excluding the cases where the change is a minor one specified by Ordinance of the Ministry of Health, Labour and Welfare), the person must obtain approval from the Minister of Health, Labour and Welfare for such change. In this case, the provisions of paragraph (2) to the preceding paragraph apply mutatis mutandis.

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Main text of the Judgment

The final appeal is dismissed.

The appellant of final appeal shall bear the cost of the final appeal.

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Reasons

Concerning the reasons for final appeal argued by the representatives designated for final appeal

1. In this case, the appellee of final appeal, who holds a patent right based on Patent No. 3398382 (hereinafter this patent and patent right are respectively referred to as the "Patent" and the "Patent Right"), seeks revocation of the trial decision issued by the Japan Patent Office (JPO) dismissing the appellee's request for a trial against the examiner's decision of refusal of the application for registration of extension of the duration of the Patent Right. The point in dispute in this case is, in a case where, prior to the approval of manufacturing and sale of a pharmaceutical product under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc. (its name prior to the amendment by Act No. 84 of 2013 was the "Pharmaceutical Affairs Act"; hereinafter referred to as the "Pharmaceuticals and Medical Devices Act" throughout the period before and after said amendment), for which an application for registration of extension of the duration of a patent right was filed (hereinafter such application is referred to as an "application for registration of extension" and such approval is hereinafter referred to as a "disposition stated as the reason for the application"), another approval of manufacturing and sale of the pharmaceutical product had been granted under the Pharmaceuticals and Medical Devices Act with regard to the same patented

invention (such approval is hereinafter referred to as a "prior disposition"), whether or not, due to the existence of the prior disposition, such case is deemed to fall under Article 67-3, paragraph (1), item (i) of the Patent Act (hereinafter referred to as the "Act") on the grounds that the disposition stated as the reason for the application is not deemed to have been necessary to obtain for the working of the patented invention to which the application for registration of extension pertained.

2. The outline of the facts legally determined by the court of prior instance is as follows.

(1) The Patent (number of claims: 11) was granted for the invention titled "vascular endothelial growth factor antagonist" for which the patent application was filed on October 28, 1992. The establishment of the Patent Right was registered on February 14, 2003.

The invention covered by the Patent relates to a composition for treating cancer, comprising a therapeutically effective amount of vascular endothelial growth factor antagonist.

(2) On September 18, 2009, with regard to the pharmaceutical product with the product name "AVASTIN 100 mg/4ml for intravenous infusion" and the generic name "bevacizumab (genetically modified)," the appellee obtained approval for partial change to the matters approved for manufacturing and sale of the pharmaceutical product under Article 14, paragraph (9) of the Pharmaceuticals and Medical Devices Act (hereinafter this approval is referred to as the "Disposition" and the pharmaceutical product subject to the Disposition is referred to as the "Pharmaceutical Product"). The active ingredient of the Pharmaceutical Product is "bevacizumab (genetically modified)," which falls within the category of "hVEGF antagonist, which is an anti-VEGF antibody" as referred to in Claim 1 of the Patent. Its effectiveness or effect is described as being "unresectable advanced or recurrent colorectal cancer," and its dosage and administration are described as follows: "in combination with other anticancer drugs, adults are ordinarily intravenously infused with bevacizumab at a dose of 7.5 mg/kg (weight) at administration intervals of at least three weeks." The manufacturing and sale of the Pharmaceutical Product constitutes the working of the patented invention covered by the Patent Right.

(3) Prior to the Disposition, another approval of manufacturing and sale had been granted under Article 14, paragraph (1) of the Pharmaceuticals and Medical Devices Act with regard to the pharmaceutical product that is identical with the Pharmaceutical Product in terms of characteristics except for the dosage and administration (hereinafter this approval is referred to as the "Prior Disposition" and the pharmaceutical product subject to the Prior Disposition is referred to as the "Prior Pharmaceutical Product"). The dosage and administration of the Prior Pharmaceutical Product are described as follows: "in combination with other anticancer drugs, adults are ordinarily intravenously infused with bevacizumab at a dose of 5 mg/kg (weight) or 10 mg/kg (weight) at administration intervals of at least two weeks." The manufacturing and sale of the Prior Pharmaceutical Product constitutes the working of the patented invention covered by the Patent Right.

(4) The Prior Disposition did not permit the manufacturing and sale of the Pharmaceutical Product for the purpose of conducting the combination treatment of XELOX treatment (giving internal medicine and administering a two-hour infusion in a three-week treatment cycle) and bevacizumab treatment. The Disposition made it possible to manufacture and sell that product for this purpose for the first time.

(5) On December 17, 2009, the appellee filed an application for registration of extension with regard to the Patent Right, on the grounds that the appellee had been unable to work the patented invention covered by the Patent Right for a certain period of time because of the necessity to obtain the Disposition, but the JPO examiner rendered a decision to refuse this application. Dissatisfied with this, the appellee filed a request for a trial against the examiner's decision of refusal.

(6) On March 5, 2013, the JPO rendered a decision (hereinafter referred to as the "JPO Decision") to dismiss the appellee's request for a trial, holding as follows. The working of the patented invention referred to in Article 67-3, paragraph (1), item (i) of the Act should be interpreted as referring to an act of manufacturing and selling the pharmaceutical product that is defined by all the matters that correspond to the matters necessary for defining the patented invention (the matters the applicant deems necessary to define the invention for which a patent is sought) among the matters stated in the written approval of the pharmaceutical product which was subject to a disposition designated by Cabinet Order referred to in Article 67, paragraph (2) of the Act (hereinafter referred to as a "Cabinet Order disposition"). The Prior Disposition already made it possible to work the patented invention covered by the Patent Right to the extent defined by all the matters that correspond to the matters necessary for defining the invention in relation to the Pharmaceutical Product, and therefore the Disposition is not deemed to have been necessary to obtain for the working of the patented invention covered by the Patent Right.

3. The purpose of the system for registration of extension of the duration of a patent right is to allow the patentee to reclaim a period of time during which the patentee has been unable to work the patented invention because of the necessity to obtain a Cabinet Order disposition. In view of the wording of Article 67-3, paragraph (1), item (i) of the Act, the case where the Cabinet Order disposition is not deemed to have been necessary to obtain for the working of the patented invention is clearly stipulated as a requirement for the examiner to refuse the application for registration of extension. Given the above, where there are a prior disposition and a disposition stated as the reason for the application, both of which were issued with regard to the manufacturing and sale of a pharmaceutical product, and if, as a result of the comparison between these dispositions, the scope of the manufacturing and sale of the pharmaceutical product subject to the prior disposition is deemed to include the manufacturing and sale of the pharmaceutical product subject to the disposition stated as the reason for the application, it should be concluded that the disposition stated as the reason for the application is not deemed to have been necessary to obtain for the working of the patented

invention to which the application for registration of extension pertains. Determination as to whether or not the disposition stated as the reason for the application was necessary for the working of the patented invention should be made exclusively by comparing the prior disposition and the disposition stated as the reason for the application, and it should not be made by making reference to all the matters that correspond to the matters necessary for defining the patented invention.

It is construed that approval of manufacturing and sale of a pharmaceutical product under the provisions of the Pharmaceuticals and Medical Devices Act makes it possible to manufacture and sell the pharmaceutical product defined for each approval with regard to all the matters to be examined in relation to the pharmaceutical product, namely, its "name, ingredients, quantity, dosage, administration, effectiveness, effect, side effects and other matters relating to the quality, efficacy and safety" (the main body of Article 14, paragraph (2), item (iii) of the Pharmaceuticals and Medical Devices Act). However, according to the purpose of the system for registration of the extension of the duration of a patent right as mentioned above, if a comparison is made between the prior disposition and the disposition stated as the reason for the application by taking into account the matters to be examined that would not directly affect the substantial identity of the relevant products as a pharmaceutical product in light of the type or subject of the patent to which the application for registration of extension pertains, this approach could lead to comparing these dispositions by taking into account the matters to be examined that would hardly be a hindrance to the working of the patented invention in relation to the pharmaceutical product, and thus finally allowing registration of an extension of the duration of the patent right, therefore it cannot be deemed to be appropriate. If so, determination as to whether or not the scope of manufacturing and sale of the pharmaceutical product subject to the prior disposition includes the manufacturing and sale of the pharmaceutical product subject to the disposition stated as the reason for the application should be made not by comparing these dispositions in form with regard to all those matters to be examined, but by comparing them with regard to the matters to be examined that would directly affect the substantial identity of the relevant products as pharmaceutical products in light of the type or subject of the patent to which the application for registration of extension pertains.

According to the above, it is appropriate to construe that where there is a disposition stated as the reason for the application and a prior disposition, and, if, as a result of the comparison between them with regard to the matters to be examined that would directly affect the substantial identity of the relevant products as pharmaceutical products in light of the type or subject of the patent to which the application for registration of extension pertains, the scope of the manufacturing and sale of the pharmaceutical product subject to the prior disposition is deemed to include the manufacturing and sale of the pharmaceutical product subject to the disposition stated as the reason for the application, the disposition stated as the reason for the application is not deemed to have been necessary to obtain for the working of the patented invention to which the application for registration of extension

pertains.

4. This reasoning can be applied in this case as follows. The patented invention covered by the Patent Right relates to a composition for treating cancer, comprising a therapeutically effective amount of vascular endothelial growth factor antagonist, and thus it is an invention of a product for which the subject matter is the ingredient of a pharmaceutical product. In the case of an invention of a product for which the subject matter is an ingredient of a pharmaceutical product, the matters to be examined when issuing said two dispositions, which would directly affect the substantial identity of the relevant products as pharmaceutical products, are the ingredients, quantity, dosage, administration, effectiveness, and effect of the pharmaceutical product. In this case, comparing the Disposition and the Prior Disposition that had been issued prior to the Disposition, the dosage and administration of the Prior Pharmaceutical Product are described as "in combination with other anticancer drugs, adults are ordinarily intravenously infused with bevacizumab at a dose of 5 mg/kg (weight) or 10 mg/kg (weight) at administration intervals of at least two weeks," whereas the dosage and administration of the Pharmaceutical Product are described as "in combination with other anticancer drugs, adults are ordinarily intravenously infused with bevacizumab at a dose of 7.5 mg/kg (weight) at administration intervals of at least three weeks." The Prior Disposition did not permit the manufacturing and sale of the Pharmaceutical Product for the purpose of conducting the combination treatment of XELOX treatment and bevacizumab treatment, but the Disposition made it possible to manufacture and sell that product for this purpose for the first time.

Given the circumstances mentioned above, in the present case, the scope of the manufacturing and sale of the pharmaceutical product subject to the prior disposition is not deemed to include the manufacturing and sale of the pharmaceutical product subject to the disposition stated as the reason for the application.

5. The court of prior instance determined the JPO Decision to be illegal because the JPO held that the Disposition was not deemed to have been necessary to obtain for the working of the patented invention to which the application for registration of extension with regard to the Patent Right pertains. According to the above, this determination by the court of prior instance can be affirmed as justifiable. The arguments by the representatives designated for final appeal cannot be accepted.

Therefore, the judgment has been rendered in the form of the main text by the unanimous consent of the Justices.

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Presiding judge

Justice KIUCHI Michiyoshi

Justice OKABE Kiyoko

Justice OTANI Takehiko

Justice OHASHI Masaharu
Justice YAMASAKI Toshimitsu

(This translation is provisional and subject to revision.)